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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/660,466	09/12/2000	Dinesh Mody	FMT1P029	6579

22434 7590 04/08/2004

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EXAMINER

ROANE, AARON F

ART UNIT	PAPER NUMBER
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3739

17

DATE MAILED: 04/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/660,466

Applicant(s)

MODY ET AL.

Examiner

Aaron Roane

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-39,41-46,48-87 and 89-104 is/are pending in the application.
- 4a) Of the above claim(s) 48-50,52,54-56,58-65,68-75,77,87 and 92-99 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36,41-46,51,53,57,66,67,76,78-86,89-91 and 100-104 is/are rejected.
- 7) ☒ Claim(s) 37-39 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Previously claims 1-35, 48-50, 52, 58-65, 68-75, 77, 87 and 92-99 were withdrawn for being drawn to non-elected subject matter. Claims 1-35, 40, 47 and 88 have since been cancelled. New claims 100-104 were added, however claims 100-104 were originally and mistakenly numbered as claims 92-96. Claims 100-104 have been correctly renumbered. However, the original claims 92-99 that were withdrawn as been drawn to a non-elected species remain.

The examiner believes Applicant mistakenly included the original claims 92-99 in the response dated 9/12/2003. Therefore the examiner has withdrawn claims 92-99 as indicated previously along with all of the other claims drawn to non-elected species (1-35, 48-50, 52, 58-65, 68-75, 77 and 87)

Claim Rejections - 35 USC § 102

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002

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do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 78-80, 85-87 and 89-91 are rejected under 35 U.S.C. 102(e) as being anticipated by Gough et al. (USPN 5,863,290).

Regarding claims 78-80, 85, 86 and 89-91, Gough et al. disclose a microwave ablation system (see third the paragraph beginning after the “summary of the invention” and the later discussion of the connection to the microwave energy source 20) as seen in figures 3-8 comprising an ablation device (16) that includes an energy delivery portion and an introducer (14) having a sharpened distal end and that is sized and dimensioned for slidable receipt of the ablation device there through. As seen for example in figure 3 (and explained in column 6, lines 30-60), the energy delivery device is made of a nitinol material and is selectively deployed to attain multiple shapes and sizes ranging from only “a few degrees from the longitudinal axis” to an obtuse angle embodiment described as a “j-hook” type. Additionally, Gough et al. disclose a device that is fully capable of performing the intended use as claimed, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the

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prior art structure is capable of performing the intended use, then it meets the claim.

Since no structural limitation is recited the prior art meets the claimed invention.

Regarding claims 82-84, Gough et al. further disclose an antenna (16) device that is preshaped and extends at an angle within the range of 0° and 90° or 45° and 135° with respect to the longitudinal axis of the shaft, see col. 4-6 and figures 1-4. Furthermore, Gough et al. further disclose a dielectric layer (18) encapsulating the antenna (16), see col. 5, lines 23-45. and figures 1-8.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 36, 41-46, 53, 57, 66, 67, 76 and 100-104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gough et al. (USPN 5,863,290) in view of Kasevich (USPN 6,233,490 B1).

Regarding claims 36, 57, 66, 67, 76 and 100, Gough et al. disclose a microwave treatment assembly comprising an elongate microwave antenna device (16) electrically coupled to the distal end of a coaxial transmission line having an inner and outer separated by a dielectric medium, an introducer or elongate probe (14) that carries a portion of the antenna device within a lumen having a sharpened distal end (14') and allowing for the slidable displacement of the antenna device beyond the distal end of the probe, see col. 4-10 and figures 1, 3, 4, 6C, 9 and 10-5. Gough et al. also disclose a microwave power source, see col. 5, lines 46-57. Gough et al. fail to explicitly recite an antenna device comprising a coaxial cable having an inner conductor, an outer conductor and a dielectric medium separating the inner and outer conductors. It is well known that microwave antennas can be connected to the distal end of a coaxial cable having an inner conductor, an outer conductor and a dielectric medium in order to serve as a waveguide and radiate energy in the microwave frequency range in order to ablate tissue. For example it is well known that waveguides for TEM mode radiation must be in a coaxial form. Kasevich discloses a microwave antenna ablation system comprising a shaft (18) and microwave antennas (22, 24 and 26) coupled to the distal end of a coaxial cables (28, 30 and 32) in order to provide hyperthermal therapy, see col. and figures 1-4. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Gough et al., as is well known in the art and shown by Kasevich, to provide an alternate means of microwave energy propagation and radiation in the form of a microwave antennas connected to the distal end of a coaxial cable having an inner conductor, an outer conductor and a dielectric medium in order to

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serve as a waveguide and radiate energy in the microwave frequency range in order to ablate tissue.

Regarding claims 41-43, 101 and 102, Gough et al. further disclose an antenna (16) device that is preshaped and extends at an angle within the range of 0° and 90° or 45° and 135° with respect to the longitudinal axis of the shaft, see col. 4-6 and figures 1-4. Furthermore, Gough et al. further disclose a dielectric layer (18) encapsulating the antenna (16), see col. 5, lines 23-45. and figures 1-8.

Regarding claims 44 and 45, Gough et al. further disclose the nitinol (NiTi) preshaped antennas (16), see col. 5, lines 3-9.

Regarding claims 46 and 53, Gough et al. disclose the claimed invention. The device disclosed by Gough et al. is fully capable of performing the intended use as claimed, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Since no structural limitation is recited the prior art meets the claimed invention.

Regarding claim 51, Gough et al. disclose the claimed invention except for explicitly reciting that the shaft diameter is less than about 3 mm.

Regarding claims 103 and 104, Gough et al. disclose the claimed invention, see above rejection to claims 36, 57, 66, 67, 76 and 100.

Claim 81 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gough et al. (USPN 5,863,290) in view of Laird et al. (USPN 6,533,780 B1).

Regarding claim 81, Gough et al. disclose the claimed invention except for making the conductive layer overlying the energy delivery device (antenna) from silver. It is well known in the art to provide electrically conductive materials that are biocompatible, such as silver. Laird et al. disclose an electrosurgical device and uses electrically conducting materials such as silver in order to provide biocompatibility between the device and the body, see col. 16, lines 27-47. It should be noted that Laird et al. is simply used to demonstrate that it is well known that electrically conductive materials be made from such metals as silver in order to be compatible with the biological surroundings.

Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Gough et al., as is well known in the art and shown by Laird et al., to make the conductive layer overlying the energy delivery device (antenna) from silver in order to provide biocompatibility between the device and the surrounding biological environment.

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Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gough et al. (USPN 5,863,290) in view of Kasevich (USPN 6,233,490 B1) as applied to claim 36 above, and further in view of Guzaik et al. (USPN 6,162,216).

Regarding claim 51, Gough et al. in view of Kasevich disclose the claimed invention except explicitly reciting that the shaft has a diameter of 3mm or less. It is well known in the art to provide an electrosurgical device that has a shaft (i.e. a catheter-type instrument) with an appropriately sized diameter in order to facilitate treatment of the biological area. Guzaik et al. disclose an electrosurgical ablation device having a shaft (20) having a diameter well within the recited range ("approximately 0.7 to 2.7 mm," see col. 4, lines 1-14) in order to facilitate the placement of the device, see col. 7-8.

Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Gough et al. in view of Kasevich, as is well known in the art and shown by Guzaik et al. to size the diameter of the shaft between "approximately 0.7 to 2.7 mm" in order to facilitate the placement of the device.

Allowable Subject Matter

Claims 37-39 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

The examiner acknowledges the amendments to the claims filed Oct. 24, 2003 (Paper #14) and the Terminal Disclaimer filed Oct. 24, 2003 (Paper #15).

The examiner has provided new art in order to make rejections. The response to arguments now follows.

Beginning on page 13, line 2, Applicant states that this application is a continuation of an earlier filed patent (Berube (USPN 6,325,796) and that a terminal disclaimer has been filed. The examiner stated above that the terminal disclaimer was taken into consideration and that new art was applied in order to reject claims 36, 41-46, 51, 53, 57, 66, 67, 76 and 100-104.

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Beginning on page 13, line 6, Applicant states that this application that Gough et al. does not conform the surface of the inner wall of the organ. Although Gough et al. do not teach this intended use, the antennas or energy delivery portion(s) (16) are certainly capable of being extended such that their tips conform to the surface of the inner wall of the organ, thus meeting the intended use. The examiner has pointed out previously, that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Since no structural limitation is recited the prior art meets the claimed invention.

A new ground for rejection has been made. **This rejection is non-final.**

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (703) 305-7377. The examiner can normally be reached on 9am - 5pm, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (703) 308-0994. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.R. *A.R.*
March 29, 2004

Michael Peffley

MICHAEL PEFFLEY
PRIMARY EXAMINER